

# **Ethical and Regulatory Aspects of Clinical Research**

**Department of Clinical Bioethics**

**Wednesdays, October 4– November 15, 2006**

**8:30 a.m. – 11:30 a.m.**

**Building 10/ Lipsett Auditorium**

## **October 4, 2006**

### **Session 1 – History of and Framework for Human Subject Research**

**8:30-8:40**

Pre-test  
Introduction to the goals and structure of the course

**8:40-9:20**

Framework for the Ethics of Research with Human Subjects  
Ezekiel Emanuel, M.D. Ph.D.  
Chair, Department of Clinical Bioethics, CC/NIH

**9:20-9:30**

Discussion

**9:30- 10:10**

Scandals and Tragedies: Beecher, Tuskegee, Willowbrook and the Rest  
John Arras, Ph.D.  
Porterfield Professor of Biomedical Ethics  
University of Virginia

**10:10- 10:20**

Discussion

**10:20-10:35**

Break

**10:35-11:20**

Purpose and Function of IRBs: Successes and Current Challenges  
Marjorie Speers PhD  
Association for the Accreditation of Human Research Protection  
Programs, Inc. (AAHRP)

**11:20-11:30**

Discussion

## **October 11, 2006**

### **Session 2 – Codes of Research Ethics, Conflicts of Interest, and Ethics of Placebos**

**8:30-9:10**

Do the Codes Apply to My Research Protocol? Nuremberg, Helsinki, the Belmont Report, CIOMS, and the Common Rule

Christine Grady, Ph.D.

Department of Clinical Bioethics, CC/NIH

- 9:10-9:20** Discussion
- 9:20-10:10** Conflicts of Interest  
Cary Gross MD  
Yale University School of Medicine
- 10:10-10:20** Discussion
- 10:20-10:35** **Break**
- 10:35-11:20** Ethics of Placebo Controlled Trials  
Frank Miller, Ph.D.  
Department of Clinical Bioethics CC/NIH
- 11:20-11:30** Discussion

**October 18, 2006**     **Session 3 – Ethics of Phase 1 oncology research and of Randomized controlled trials**

- 8:30-9:10** Ethics of Phase I Oncology Research  
Ezekiel Emanuel MD PhD  
Department of Clinical Bioethics CC/NIH
- 9:10-9:20** Discussion
- 9:20- 10:00** Ethics of Randomized Clinical Trials: Clinical Equipoise  
Robert Truog, M.D.  
Professor of Anesthesiology & Medical Ethics  
Harvard Medical School
- 10:00- 10:10** Discussion
- 10:10- 10:25** **Break**
- 10:30- 11:30** **Mock IRB**

**October 25, 2006**     **Session 4 –Ethical issues in subject selection, research with children and CAM research**

- 8:30-9:15** Subject Selection and Recruitment  
Christine Grady, Ph.D.

Department of Clinical Bioethics, CC/NIH

<b>9:15- 9:25</b>	Discussion
<b>9:25-10:10</b>	Ethics of Research with Children Alan Fleischman MD NICHD/NIH Senior Vice President, New York Academy of Medicine
<b>10:10-10:20</b>	Discussion
<b>10:20-10: 35</b>	<b>Break</b>
<b>10:35- 11:20</b>	CAM Research: Unique challenges in assessing research risks and benefits. John Tilburt MD, MPH NCCAM Department of Clinical Bioethics, CC/NIH
<b>11:20- 11:30</b>	Discussion

<b><u>November 1, 2006</u></b>	<b><u>Session 5 – Informed Consent and impaired capacity to consent</u></b>
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<b>8:30-9:10</b>	Informed Consent: the ideal and the reality Christine Grady, Ph.D. Department of Clinical Bioethics, CC/NIH
<b>9:10-9:20</b>	Discussion
<b>9:20-10:00</b>	Research Involving Persons at Risk for Impaired Decision-Making Don Rosenstein, M.D. Chief, Psychiatry Consult-Liaison Service Deputy Clinical Director, NIMH/NIH
<b>10:00-10:10</b>	Discussion
<b>10:10-10:25</b>	<b>Break</b>
<b>10:30-11:30</b>	Participant panel

**November 8, 2006**    **Session 6 – Ethical issues in International Research**

- 8:30- 9:15**                      International research: Ethical challenges in the field  
Elizabeth Higgs, MD  
Deputy Director Collaborative Clinical Research Branch  
Office of Clinical Research, NIAID/NIH
- 9:15-9:25**                      Discussion
- 9:25- 10:10**                      Exploitation  
Alan Wertheimer PhD  
Department of Clinical Bioethics CC/NIH  
Professor Emeritus- University of Vermont
- 10:10-10:20**                      Discussion
- 10:20- 10:35**                      Break
- 10:35- 11:20**                      Fair benefits, ancillary care, and post trial considerations  
Reidar Lie MD PhD  
Department of Clinical Bioethics, CC/NIH
- 11:20- 11:30**                      Discussion

**November 15, 2006**    **Session 7 – Genetics and Stored Tissue**

- 8:30-9:15**                      Ethical Issues in the Use of Stored Tissue  
Sara Chandros Hull, Ph.D.  
Medical Ethics Branch, NHGRI/NIH
- 9:15-9:25**                      Discussion
- 9:25-10:05**                      **Case discussion**
- 10:05-10:20**                      **Break**
- 10:20 -11:05**                      Ethical Issues in Genetics Research  
Gail Geller  
Johns Hopkins University School of Public Health
- 11:05-11:15**                      Discussion
- 11:15- 11:30**                      Post tests and evaluations